K050464

Confidential

MAY 1 1 2005

510(k) Summary

Submitter
Ulti Med Inc.
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St. Paul, Minnesota
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Date Prepared
21 February 2004

Name of Device

Common Name:	Pen Needles
Proprietary Name:	UltiCare™ Disposable Pen Needles (sizes varying between 31 Gauge x 3/16" and 29 Gauge x 1/2")
Classification Name:	Hypodermic single lumen needles
Regulation:	880.5570
Class:	Class II
Product Code:	FMI

Predicate Devices
The UltiCare Disposable Pen Needles are substantially equivalent in intended use, function and basic composition to the currently marketed Becton Dickinson B-D Ultra-Fine III Pen Needle; Model 31 gauge x 3/16", K002938, and to the Becton Dickinson B-D Ultra-Fine Original Pen Needle (29 gauge x 1/2"), K031200.

Device Description
The UltiCare Disposable Pen Needles are sterile, single-use, type A, hypodermic single lumen needles designed for use with insulin pen injector devices. The UltiCare Disposable Pen Needles consist of a double-ended cannula, a needle hub, a needle shield and the needle primary container. The UltiCare Disposable Pen Needles are non-toxic and non-pyrogenic, and are available in a variety of needle sizes (29 gauge to 31 gauge) and lengths (3/16" to 1/2").

Intended Use
The UltiCare disposable pen needles are used with insulin pen injector devices for the subcutaneous injection of insulin in the treatment of diabetes.

Technological Characteristics
The UltiCare Disposable Pen Needles have similar technological characteristics to the currently marketed predicate devices listed above. The UltiCare Disposable Pen Needles meet the following standards:

ISO 11608-2, Pen-injectors for Medical Use - Part 2: Needles - Requirements and Test Methods
ISO 9626, Stainless Steel Needle Tubing for Manufacture of Medical Devices
ISO 7864, Sterile Hypodermic Needles for Single Use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2005

Ulti Med, Incorporated
C/O Ms. Carole Stamp
Principal Regulatory and Quality Advisor
Regulatory and Clinical Research Institute, Incorporated
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416-1334

Re: K050464
Trade/Device Name: UltiCare Disposable Pen Needles
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: February 21, 2005
Received: February 25, 2005

Dear Ms. Stamp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050464

Device Name: UltiCare™ Disposable Pen Needles

Indications for Use:

The UltiCare disposable pen needles are used with insulin pen injector devices for the subcutaneous injection of insulin in the treatment of diabetes.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050464